## REMARKS

In the Office Action dated April 14, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following five separate and distinct inventions:

Group I. Claims 1-33, drawn to methods to determine the onset or predisposition to neoplasm by assaying for a set of sequences, classified in class 435, subclass 6.

Group II. Claims 34-63, and 82, drawn to nucleic acids and kits with said nucleic acids, classified in class 536, subclass 23.1.

Group III. Claims 64-77, and 82, drawn to proteins and kits with said proteins, classified in class 530, subclass 350.

Group IV. Claims 78-81, drawn to a method of treatment of inappropriate cell growth with nucleic acids, classified in class 574, subclass 44.

Group V. Claims 78-81, drawn to a method of treatment of inappropriate cell growth with proteins, classified in class 514, subclass 2.

In addition, the Examiner states that upon election of Group I, II or IV, a single nucleic acid sequence or a specific combination of sequences must also be elected. In addition, the Examiner states that Applicants are further required to distinctly point out the location in the drawings, figures, or SEQ IDS to which the elected sequence is drawn, and to include the Genbank numbers or any other identifier of the elected sequence, the table or figure number, and the row or column location in the table.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, claims 1-33, and SEQ ID NO: 7. Disclosure relating to the use of SEQ ID NO: 7 in the claimed methods is found in the specification, e.g., at page 25, line 29; page 28, lines 24 and 29; page 29, lines 4 and 8; and pages

33-39. As set forth in Table 2 on page 79 of the specification, SEQ ID NO: 7 corresponds to clones 12-2f and 8-2d, and additional clone information is found in Genbank under gi/18104896/gb/AC023302.9. Additional disclosure relating to SEQ ID NO: 7 is found in Tables 3, 5-7, 9-11, 13, and 15 on pages 115-127 (see references to clones 8-2d and 12-2f in these tables). Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions that are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, the Examiner has admitted that Groups I and II are related as product and process of use. Thus, Groups I and II are clearly related and are *not* "independent and distinct". The interdependence of Groups I-II is confirmed --indeed, it is mandated-- by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application

which Applicants have filed. For example, an application claiming the nucleic acids of Group II is required to disclose inter alia how to make and use the nucleic acids. In other words, a description of the means and method for using the subject nucleic acids is a mandatory part of the application to the nucleic acids themselves. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product and its use, are necessarily interdependent, not independent, from each other.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

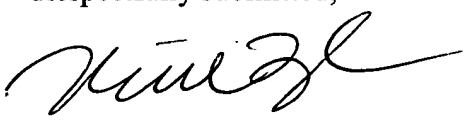
Furthermore, in connection with the election of SEQ ID NO: 7, Applicants respectfully submit that Group I includes claims that recite a combination of sequences, including a combination of SEQ ID NO: 7 with other sequences; for example, claims 19-21 and 23-28. In this connection, Applicants respectfully direct the Examiner's attention to MPEP 803.04, where it is stated that the presence of one novel and nonobvious sequence within a combination should render the entire combination allowable. Accordingly, it is understood that once the claimed

method based on the elected sequence (i.e., SEQ ID NO: 7) is found to be allowable, methods that employ a combination of nucleic acid sequences including SEQ ID NO: 7 should be included in the examination and be found allowable as well.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the defined five groups and the various sequences, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



Xiaochun Zhu
Registration No. 56,311

SCULLY, SCOTT, MURPHY & PRESSER, P. C.
400 Garden City Plaza-STE 300
Garden City, New York 11530
(516) 742-4343
XZ:ab